

Drawings

Applicant believes that the identified claims are fully supported in the application as originally filed. For example, Figs. 2 and 9 include a structure 48/108 which is shown in cross-sectional detail in Fig. 10. The structure meets the limitations of the independent claims 1 and 13 and consists of a nested geometric structure (claims 3 and 7) and comprises nested hexcels (claims 4 and 8). Accordingly, all of the features of the claims are supported by the drawings.

However, in order to eliminate any doubt regarding support, Applicants have added new Figure 11 and 12 which correspond to Figures 4 and 10, and the accompanying text regarding those figures from the parent case to this CIP. The parent cases have been explicitly incorporated by reference in the application as filed, such as at page 1, lines 17-19. A new sheet of figures including Figs. 11 and 12 (old Fig. 4 and Fig. 10) is enclosed.

Art Based Rejections

The main reference relied upon by the Examiner, Hamas, is easily distinguishable from the claims. Hamas discloses a integrated implant device having projecting prongs. Significantly, however, the attached prongs and external covering are integrated with the underlying device. Applicants claims now include the limitation that the covering is “separated from and unattached to the said device”. There is no teaching or suggestion in Hamas of such physical detachment. As one example of such detachment, Figures 1 and 2 clearly show the covering as being unattached to the underlying device. As such, the claims are free of the art.

Double Patenting

Applicant will file a Terminal Disclaimer as requested. Since this is a post-GATT case, the term will not be impacted.

Applicant would request that the undersigned be contacted by telephone if any matter remains regarding the allowability of these claims.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "Version with markings to show changes made."

Prompt and favorable action on the merits of the claims is earnestly solicited. If any minor issues remain, please contact Applicants' undersigned representative at 949-567-2300.

Respectfully submitted,

LYON & LYON LLP

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By: 

David Murphy
Reg. No. 31,125

DBM/dnd
633 West Fifth Street, Suite 4700
Los Angeles, California 90071-2066
(949) 567-2300 or (213) 489-1600

“Version with markings to show changes made”

In the specification:

Page 5, before line 23, the following paragraphs have been inserted:

FIG. 11 is a perspective view of an implant covering cut from a single sheet of PTFEe placed around a silicone elastomer shell.

FIG. 12 shows a perspective view of detail of PTFEe sheet material with a partial thickness pattern of simple cuts and/or channels which results in numerous individual villi of PTFEe and great irregularity of the surface of the material. Additional patterns of cuts or troughs may be made along any other axis as indicated, for example, by the arrows.

Page 15, before line 5, the following paragraphs have been added:

A covering for an implant may be constructed substantially of a single sheet of PTFEe as shown for example in FIG. 11. A single sheet of PTFEe 40 is cut so as to permit it to be wrapped around the implant 110. Projectile tongues 42 may be fastened together or may be attached to separate PTFEe sheets 144 and 146 which serve as cap and bottom pieces. Appropriate cuts 148 are made in the single PTFEe sheet 140 to permit stretching of the sheet in various directions.

The implant coverings usable in connection with this invention may be manufactured from any material which promotes limited tissue ingrowth into the material, and has a high biocompatibility and low reactivity and disorganizes scar tissue at the implant/body interface. Expanded PTFE (PTFEe) is a preferred material for this invention. PTFEe is sold under the tradename Gortex and is readily available. The expanded ultrastructure of this material is associated with a high degree of ultramicroporosity which invites tissue ingrowth. The material is approximately 50% air by volume. It is extremely strong yet soft, smooth, pliable, compressible and

stretchable. Gortex is readily available in sheet form of various thicknesses, as round filaments of various diameters, and as tubes of various diameters and wall thicknesses. PTFEe sheeting stretches to a limited extent along a given axis, however resists stretching along all axes simultaneously. It is extremely biocompatible having been used in more than 700,000 clinical uses with no confirmed cases of material rejection. PTFEe is incorporated into surrounding tissue and is minimally encapsulated by collagen. The material is extremely strong and thereby would reduce the need for reoperation for material fatigue. It resists flexural fatigue by acting like a chain when bending forces are applied. However, it is easily cut by a knife or by using die cutting techniques. It lends itself well to machine manufacturing methods including stitching.

In the claims:

The claims have been amended as follows:

Claim 100 has been cancelled.

Claim 1 (Twice Amended) A sheet-like material for implantation in a body comprising:
~~covering for an implantable device comprising~~

a sheet of material having a first surface and a second surface,

~~a first surface,~~ the first surface being non-textured, and

~~a~~ the second surface having ridges and valleys,

characterized in that the ~~covering~~ sheet-like material is separated from and unattached to
structures other than said body ~~the said device~~.

Claim 2 (Amended) The ~~covering~~ sheet-like material of claim 1 further comprising ePTFE material.

Claim 3 (Amended) The ~~covering~~ sheet-like material of claim 1 wherein the ridges and valleys of the second surface form nested geometric structures.

Claim 4 (Amended) The ~~covering~~ sheet-like material of claim 3 wherein the nested geometric structures comprise nested hexcels.

Claim 5 (Twice Amended) An implantable ~~device-covering~~ sheet-like material comprising:
a sheet of flexible material having first and second surfaces,
the first surface being flat,
the second surface having peaks and troughs and being adapted to interface with body tissues ~~characterized in that the covering is separated from and unattached to the said device.~~

Claim 6 (Amended) The ~~covering~~ sheet-like material of claim 5 further comprising ePTFE material.

Claim 7 (Amended) The ~~covering~~ sheet-like material of claim 5 wherein the peaks and troughs of the second surface form nested geometric structures.

Claim 8 (Amended) The ~~covering~~ sheet-like material of claim 7 wherein the nested geometric structures comprise nested hexcels.

Claim 13 (Twice Amended) An implantable ~~device-covering~~ sheet-like material comprising:
a sheet of flexible material having first and second surfaces,
the first surface being less-textured than the second surface,
the second surface being textured and having first and second planar surfaces, the first and second planar surfaces being in non-coplanar relation characterized in that the ~~covering~~ sheet-like material is separated from and unattached to the ~~said device~~ body.

Claim 14 (Amended). The ~~covering~~ sheet-like material of claim 13 further comprising PTFEe material.

Claim 94 (Amended) The ~~covering~~ sheet-like material of claim 1 wherein the ridges and valleys have a plurality of regions of varying heights, the tallest regions having a substantially planar upper surface, the planar surface defining a first plane, and the lowest regions defining a second plane, where the second plane is non-coplanar with the first plane.

Claim 95 (Amended) The ~~covering~~ sheet-like material of claim 1 wherein the second surface comprises a pattern.

Claim 96 (Amended) The ~~covering~~ sheet-like material of claim 95 wherein the pattern is predictable.

Claim 97 (Amended) The ~~covering~~ sheet-like material of claim 95 wherein the pattern is repetitive.

Claim 98 (Amended) The ~~covering~~ sheet-like material of claim 95 wherein the pattern is uniform.

Claim 99 (Amended) The ~~covering~~ sheet-like material of claim 95 wherein the surface includes a plurality of hexcells.

Claim 101 (Amended) The ~~covering~~ sheet-like material of claim 95 wherein the pattern includes geometric patterns.

Claim 102 (Amended) The ~~covering~~ sheet-like material of claim 101 wherein the geometric pattern includes squares.

Claim 103 (Amended) The ~~covering~~ sheet-like material of claim 101 wherein the geometric pattern includes circular patterns.

Claim 104 (Amended) The ~~covering~~ sheet-like material of claim 1 wherein the lateral widths of the ridge regions and the valley regions differ.

Claim 105 (Amended) The ~~covering~~ sheet-like material of claim 1 wherein the lateral width of the ridge regions is less than the width of the valley regions.

Claim 106 (Amended)The ~~covering~~ sheet-like material of claim 1 wherein the ridges and valleys include planar regions and the ratio of the height of the second plane to the first plane measured relative to the first side is substantially 90% or less.

Claim 107 (Amended)The ~~covering~~ sheet-like material of claim 106 wherein the ratio of the height of the second plane to the first plane measured relative to the first side is substantially 80% or less.

Claim 108 (Amended)The ~~covering~~ sheet-like material of claim 106 wherein the ratio of the height of the second plane to the first plane measured relative to the first side is substantially 70% or less.

Claim 109 (Amended)The ~~covering~~ sheet-like material of claim 106 wherein the ratio of the height of the second plane to the first plane measured relative to the first side is substantially 50%.

Claim 110 (Amended)The ~~covering~~ sheet-like material of claim 1 wherein the sheet-like material is a laminated structure.

Claim 111 (Amended)The ~~covering~~ sheet-like material of claim 110 wherein the ~~covering~~ sheet-like material is a multi-laminate structure.

Claim 112 (Amended)The ~~covering~~ sheet-like material of claim 1 wherein the top surface of the ridge regions is substantially parallel to the surface of the valley regions.

Claim 113 (Amended)The ~~covering~~ sheet-like material of claim 1 wherein the second surface is arranged to stimulate high tissue ingrowth.

Claim 114 (Amended) The ~~covering~~ sheet-like material of claim 1 wherein the second surface is arranged to disorganize scar tissue.

Claim 115 (Amended)The ~~covering~~ sheet-like material of claim 1 wherein the lowest region of the second surface comprises a fabricated surface.

Claim 116 (Amended)The ~~covering~~ sheet-like material of claim 1 further including a device for implantation in the body, wherein the ~~covering~~ sheet-like material is disposed adjacent the device.

Claim 117 (Amended)The ~~covering~~ sheet-like material of claim 116 wherein the second surface is oriented away from the device.

Claim 118 (Amended)The ~~covering~~ sheet-like material of claim 116 wherein the second surface is oriented toward from the device.

Claim 119 (Amended)The ~~covering~~ sheet-like material of claim 116 wherein the device is a prosthetic device.

Claim 120 (Amended)The ~~covering~~ sheet-like material of claim 119 wherein the prosthetic device is an implant.

Claim 121 (Amended)The ~~covering~~ sheet-like material of claim 119 wherein the implant is a gel filled implant.

Claim 122 (Amended)The ~~covering~~ sheet-like material of claim 95 wherein the pattern includes a plurality of parallel wells.

Claim 123 (Amended)The ~~covering~~ sheet-like material of claim 94 wherein the second plane is lower than the first plane by at least 7% of the thickness of the structure.

Claim 124 (Amended)The ~~covering~~ sheet-like material of claim 94 wherein the second plane is lower than the first plane by at least 17% of the thickness of the structure.

Claim 125 (Amended)The ~~covering~~ sheet-like material of claim 94 wherein the second plane is lower than the first plane by at least 27% of the thickness of the structure.

Claim 126 (Amended)The ~~covering~~ sheet-like material of claim 94 wherein the second plane is lower than the first plane by substantially 50% of the thickness of the structure.